Ingredient Definitions Committee
10/19/18 meeting Recommendations & Minutes

Recommendations to the Board and Association membership:
When needed, new text is presented in the committee minutes, appendix A (page 5).

1) Delete Definition T73.311 Hydrogenated Glycerides if T73.311 (A) is accepted by Association membership.

2) Publish in the OP a new Official Definition for 90.9 25-hydroxyvitamin D₃ reflecting edits on 10/19/18 to combine all intended uses and remove the alternate name. (Replaces the recommendation from the 10/5/18 IDC meeting.)

Board Action:
To be considered in November 2018

Association Action:
To be considered in January 2019

Edits to the OP. No need for further Association action:
A.) Editorial Change: “Common and Usual” on page 352 & 510 (2019 OP) to the correct terminology of “Common or Usual”.

B.) Edit vitamin table 90.25 to remove 25-hydroxyvitamin D₃ once the Association accepts definition 90.9
The meeting was convened at 11:33 am PST via webinar by Chairperson Richard Ten Eyck.

1) Role Call of Committee members
   Richard Ten Eyck, Erin Bubb, David Beard, Brett Boswell, Ken Bowers (via proxy - Erin Bubb), Bob Church (via proxy – Dave Phillips), Dave Dressler, James Embry, Maggie Faba, George Ferguson, Jacob Fleig, Steve Gramlich, Ali Kashani, Dan King, Mark LeBlanc, Rick Manthei, Dave Phillips, Tom Phillips, Nathan Price, Laura Scott, Mika Alewynse (voting member for FDA), Charlotte Conway (no vote), Kent Kitade (no vote), Jennifer Kormos (no vote)

   A quorum was present 21/25.

2) Accept Minutes from 10/5/18 IDC meeting
   Jacob Fleig (via BIN) moves to ACCEPT the minutes. Brett Boswell (via BIN) seconds. MOTION PASSES.

3) Investigator recommendations to move tentative to official or not?
   a.) T73.311 Hydrogenated Glycerides – Yes, Richard
      Jacob Fleig moves to ACCEPT recommendation to delete the definition if T73.311 (A) is accepted by association membership. Steve Gramlich seconds. MOTION PASSES.

   Richard Ten Eyck and Leah Wilkinson from AFIA ask if there are any issues for States to accept the tentative definition. Kristi Smedley agreed with only having one tentative definition and asked if T73.311(A) can go official instead of in as tentative. Richard Ten Eyck stated that the minutes from the October 5th webinar have it as tentative and asked if it would be the preference to bring it in as official. Kristi Smedley stated that it would fulfill the requirements for the States that require official definitions. Idaho requires official definitions. Tom Phillips states that they have some regulatory discretion but does rely on the official definitions. Charlotte Conway asked if there was a lot of concern to remove the tentative process in the survey. George Ferguson stated that the IDC does not represent all the States.

4) New Definitions, deletes & edits:
   a) Update Chapter 6 header to clarify ODI nomenclature
to correct language of “Common or Usual” - Richard
Mika Alewynse moves to ACCEPT the recommended editorial change. Ali Kashani seconds. MOTION PASSES.

b) Edit the comma out of OP common names (list provided in BIN) – Phillips
This topic was discussed, but no motion was made. Revisit the topic if needed after ODI is launched.

c) Update Guidelines document in chapter 6 – Sue
   a. Discuss the length of tentative first
   The topic was discussed, but no motion was made. Committee will discuss again in January. Members should forward questions to the workgroup so the document can be ready for voting at midyear.

d) Vitamin names (placeholder) need recommendations – Tom
   a. Vitamin A
   b. Vitamin C
   c. Vitamin E
   No proposal ready for discussion today.

e) 90.9 25-hydroxy vitamin D₃ – Tom / CVM
   Tom Phillips moves to strike Calcifediol text from the language. Mika Alewynse second. MOTION PASSES.

   Tom Phillips moves to ACCEPT the replacement of the definition that was voted on in the October 5, 2018 webinar with this amended definition as official. Erin Bubb seconds. MOTION PASSES.

   New language was prepared that merge the two CFR definition. Proposes intended use for all chickens and adds an alternative name, calcifediol. Charlotte Conway stated that FDA is not in favor of adding in the alternative name. Leah Wilkinson asked if this was reviewed by the Firm that sponsored the food additives (same Firm both food additives). Tom Phillips asked if this should be tabled until the Firm can be consulted. Mika Alewynse stated that the Firm has seen the CFR (part of the FAP process). There was discussion on whether to add the alternative name, calcifediol, or not. It was decided not to add the language, and the proposed definition would be amended to remove it.

5) Work Group Reports
   a) GRAS verification workgroup report – Sue Hays
      Next committee meeting is on the October 29th. The workgroup will have an update at the IDC meeting January.
b) Non-Defined List Workgroup - Kent Kitade
No Update was provided.

c) Confusing Pet Food Names Workgroup – Brett Boswell
No actions are ready for committee consideration.

d) Guidelines For requesting Definitions Editing Workgroup – tbd
Discussed during agenda item 4(c).

e) ODI Subcommittee? (new) – tbd
Richard Ten Eyck thought that there might be a need for a communication bridge between the IDC and Feed Labeling Committee for ODI topics and thought that this might be handled by a new subcommittee. Dave Phillips stated that an ODI work group in feed labeling committee needs to be formed and expects it to be formed in the next month or so. No action taken by IDC.

6) Discussions:
   a) **Hemp** Update – Bob C. & Brett B., Scott Z. // 9/7/18 no change in status, not approved for animal feeding // direct questions to Bob or Brett.
   Brett Boswell stated there has been no change in status. Richard Ten Eyck had a question from an Oregon feed mill asking if they can put it in horse feed. People are still trying to use hemp, but there have been no approvals for use in animal food.
   b) GRAS policy discussion – Doug Lueders
   c) Status on high profile ingredients (if needed) – Richard / CVM
   d) Discussion of common human foods in pet food (placeholder)
   e) Any activities needing 19 – 20 Association funding?
   f) Set Webinar **meeting dates** for:
      1. April XX 2019
   g) Next Meeting, AAFCO Midyear, Savannah Georgia, January 22, 2019
      10:30AM EST

Meeting adjourned 12:53pm

Minutes approved 11/7/18 by a vote of 13/25 committee members with one abstain.
Appendix A for 10/19/18 IDC meeting

90.9 25-hydroxyvitamin D₃

The food additive, 25-hydroxyvitamin D₃, may be safely used in accordance with the following prescribed conditions:

(a) The additive is used or intended for use as a source of vitamin D₃ activity in animal feed or drinking water in accordance with good manufacturing and feeding practices as follows:

1. In feed or drinking water of layer and breeder chickens not to exceed 69 parts per billion (ppb) in feed or 34.5 ppb in drinking water.
2. In feed or drinking water of turkeys not to exceed:
   i. 92 ppb in feed; or
   ii. in drinking water, 25 ppb for turkeys up to 3 weeks of age, 36 ppb for turkeys from 4 to 11 weeks of age, or 45 ppb for turkeys over 11 weeks of age.

(b) The additive consists of not less than 94 percent 25-hydroxyvitamin D₃ (9,10-secocholesta-5,7,10(19)-triene-3β, 25-diol).

(c) The additive meets the following specifications:

1. Not more than 1 percent of any individual sterol.
2. Not more than 5 percent water.
3. Not more than 20 parts per million (ppm) lead.
4. Not more than 20 ppm aluminum.
5. Not more than 1.0 percent solvents and non-detectable levels of 2', 4', 5', 7' tetraiodofluorescin.
6. Not more than 1 ppb 1,25-dihydroxycholecalciferol.

(d) To assure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act, the label and labeling shall contain:

1. The name of the additive.
2. A statement to indicate the maximum use level of 25-hydroxyvitamin D₃ must not exceed 69 ppb in feed or 34.5 ppb in drinking water for layer and breeder chickens.
3. A statement to indicate for turkeys the maximum use level of 25-hydroxyvitamin D₃ must not exceed 92 ppb in feed; or in drinking water, 25 ppb for turkeys up to 3 weeks of age, 36 ppb for turkeys from 4 to 11 weeks of age, or 45 ppb for turkeys over 11 weeks of age.
4. Adequate use directions to ensure that 25-hydroxyvitamin D₃ (and all premixes) is uniformly blended throughout the feed or drinking water.
5. An expiration date on all premix labeling.
6. A statement on all premix labeling (feed and drinking water forms) that 25-hydroxyvitamin D₃ cannot be used simultaneously in both feed and water.

21 CFR 573.550, 584.725 (Adopted 2019 ver 1)